



Information Pharmacists Can Use on: Closing the Coverage Gap

The Affordable Care Act includes provisions to close the Medicare Part D prescription drug coverage gap (also known as the “donut hole”) to make prescription drugs more affordable for people with Medicare. The first step in closing the coverage gap was the mailing of the one-time \$250 rebate check to most people who reached the coverage gap in 2010. The second step to closing the coverage gap starts January 1, 2011.

Starting in January 2011, people with Medicare who have Part D, but don’t get Extra Help (the low-income subsidy), will get a 50% discount under the Medicare Coverage Gap Discount Program on “applicable” drugs at the point-of-sale and a 7% increase in coverage for all other covered Part D drugs (e.g., generic drugs and supplies associated with the delivery of insulin) while they are in the coverage gap. Over the next 10 years, prescription drug coverage will continue to increase for all covered drugs in the coverage gap so what people pay during the gap will continue to decrease until it reaches 25% in 2020.

What are “Applicable” Drugs?

Applicable drugs are Part D prescription drugs approved under new drug applications (NDAs) or licensed under biologics license applications (BLAs). These are generally covered brand-name Part D drugs including insulin and Part D vaccines. Applicable drugs also include Part D prescription drugs that are commonly considered generic drugs, but actually have been FDA approved under NDAs. These drugs must be covered by a signed discount agreement to be covered under Part D. Beginning in 2011, only those applicable drugs that are covered under a signed manufacturer discount agreement with the Centers for Medicare & Medicaid Services (CMS) will be covered under Part D. All other covered Part D drugs (e.g. generic drugs approved under abbreviated new drug applications (ANDAs) and supplies associated with the delivery of insulin) may continue to be covered by Part D plans irrespective of a signed manufacturer agreement.



How will the Medicare Coverage Gap Discount Program work?

Drug manufacturers must sign agreements with CMS to participate in the Medicare Coverage Gap Discount Program. The agreement specifies that all of the manufacturers' applicable drugs will automatically be discounted by 50% at the point-of-sale for coverage gap claims beginning January 1, 2011. **The discount doesn't include the cost of the dispensing fee.** The full cost of the drug will count as out-of-pocket spending for the purposes of reaching catastrophic coverage.

Example: Mrs. Anderson reaches the coverage gap. She goes to her pharmacy to fill a prescription for an applicable drug. The price for the drug is \$60 and the dispensing fee is \$2. Once the 50% discount is applied, the cost of the drug is \$30. The \$2 dispensing fee is added to the \$30 discounted amount. Mrs. Anderson will pay \$32 for the prescription, but the entire \$62 (both what Mrs. Anderson and the manufacturer pay) will be counted as out-of-pocket spending and will help Mrs. Anderson get out of the coverage gap.

If a drug manufacturer doesn't sign a discount agreement with CMS, its applicable drugs won't be covered under Part D, and Part D sponsors won't be allowed to grant an exception or provide a transition for such drugs. People may still buy the drug at its full price, but the cost won't count toward getting out of the coverage gap. Medicare Part D plans will review coverage gap claims to determine the person's eligibility and if the drugs are eligible for the discount.

How will I know which manufacturers have signed a Coverage Gap Discount Program agreement with CMS?

CMS has published a listing of companies that have signed an agreement along with the associated five-digit labeler codes on its Web site. The listing of labeler codes and manufacturers can be found at www.cms.gov/PrescriptionDrugCovGenIn. Select "Part D Information for Pharmaceutical Manufacturers."

How should pharmacies prepare for the Coverage Gap Discount Program?

Pharmacies should do the following to prepare for the Discount Program launch on January 1, 2011:

1. **Manage Supply Chain**—Pharmacies should work with Medicare Part D contractors to review the list of labeler codes on the CMS Web site to determine if their inventories have applicable drugs. This can be done by comparing inventory against CMS's list of labeler codes that are covered by a signed agreement in 2011. The Medicare Coverage Gap Discount Program labeler code list can be used to identify which manufacturers' applicable drugs will continue to be covered under Medicare Part D in 2011.
2. **Educate Staff**—Pharmacy staff should be made aware of the Medicare Coverage Gap Discount Program and be prepared to answer patient inquiries about it.

How will Medicare increase its coverage for all other Part D drugs?

In 2011, Medicare will begin by increasing its standard coverage by paying 7% of the cost for all other non-brand name Part D drugs (e.g., generic drugs and supplies associated with the delivery of insulin) during the coverage gap, including the dispensing fee. This means people with Medicare who reach the coverage gap will pay 93% of the cost. Part D coverage will continue to increase each year and the amount people pay **will decrease each year** until 2020, when the amount eligible people pay for these drugs will be 25% of the cost. The standard rules for calculating the person's out-of-pocket costs apply.

Example: Mrs. Anderson reaches the coverage gap. She goes to her pharmacy to fill a prescription for a covered generic drug. The price for the drug is \$20, and the dispensing fee is \$2. Once the 7% coverage is applied to the \$22, she will pay \$20.46 for the covered generic drug and only \$20.46 will be counted as out-of-pocket spending that will help Mrs. Anderson get out of the coverage gap.

Who is eligible for the new savings while in the coverage gap?

People who meet all of the following criteria are eligible for discounts under the Medicare Coverage Gap Discount Program:

- They are currently enrolled in a Medicare Prescription Drug Plan (including people enrolled in employer group health and waiver plans), or a Medicare Advantage Plan that includes prescription drug coverage
- They don't get Extra Help (a Medicare program to help people with limited income and resources pay Medicare prescription drug costs)
- They have reached the coverage gap

Note: Some people are in Medicare drug plans that don't have a coverage gap, but they will still be eligible to get a discount on brand-name prescriptions once they reach the defined standard initial coverage limit (ICL). For 2011, the defined standard ICL is \$2,840.

How will someone know what discounts have been applied?

The Explanation of Benefits (EOB) notice, that people with Medicare receive, will show the amount of the monthly prescription drug costs funded by the manufacturers.

How do the discounts work if someone is enrolled in a State Pharmacy Assistance Program (SPAP)?

People with Medicare who are eligible for the discounts and enrolled in a State Pharmacy Assistance Program (SPAP), or any other program that provides coverage or financial assistance for Part D drugs (other than Extra Help), still get the 50% discount on applicable drugs in the coverage gap. The 50% discount is applied to the price of the drug before any SPAP or other coverage.

What if someone gets discounts from a drug manufacturer?

Patient assistance programs offered by manufacturers don't have the same rules as SPAPs. People should check with the manufacturer to determine if their assistance program will change.

Does the discount apply to people who have enhanced Part D coverage?

Yes. A discount may be applied after their coverage has been applied to the cost of the drug. The 50% discount will apply to the remaining amount they owe. For example, Mrs. Anderson is in an enhanced Part D plan. Her plan has an enhanced brand-name drug benefit of 60%. After she reaches the initial coverage limit, she goes to her pharmacy to fill a prescription for a brand-name drug. The negotiated price of the drug is \$100. After the plan's benefits are applied (60% off of \$100 = \$40), the 50% discount is applied to the remaining \$40 amount. Mrs. Anderson will pay \$20 for her prescription (plus any dispensing fee), but \$40 will count as out-of-pocket spending and help Mrs. Anderson get out of the coverage gap.

Who is responsible for handling disputes if someone believes they should have received a discount but didn't?

Part D plans must handle inquiries and complaints about the Medicare Coverage Gap Discount Program. Individuals who think they should get a discount need to call their Part D plan. The plan's phone number is located on the individual's plan membership card. If the individual and drug plan disagree on whether a discount is owed, the individual may use the existing coverage determination and appeals process to resolve the dispute.

They can also call 1-800-MEDICARE (1-800-633-4227) to file a complaint. TTY users should call 1-877-486-2048.

Can someone file an exception for a drug if the manufacturer isn't participating in the Medicare Coverage Gap Discount Program?

No. If a manufacturer doesn't have an agreement with CMS to participate in the Discount Program, no applicable drugs labeled by that manufacturer will be covered under Part D. All other covered Part D drugs (e.g. generic drugs and supplies associated with the delivery of insulin) by such manufacturers may continue to be covered by Part D plans. In 2011, manufacturers that produce over 99% of the brand-name drugs used by people with Medicare are participating in this program.

Can retroactive adjustments affect the discount?

Yes, if changes are made to an individual's eligibility or benefit it could affect the discount. These adjustments would be reported on the monthly Explanation of Benefits (EOB) notice that people with Medicare receive. It will show the amount of the monthly prescription drug costs funded by the manufacturers. People should contact their plan if they think they are eligible for an adjustment.

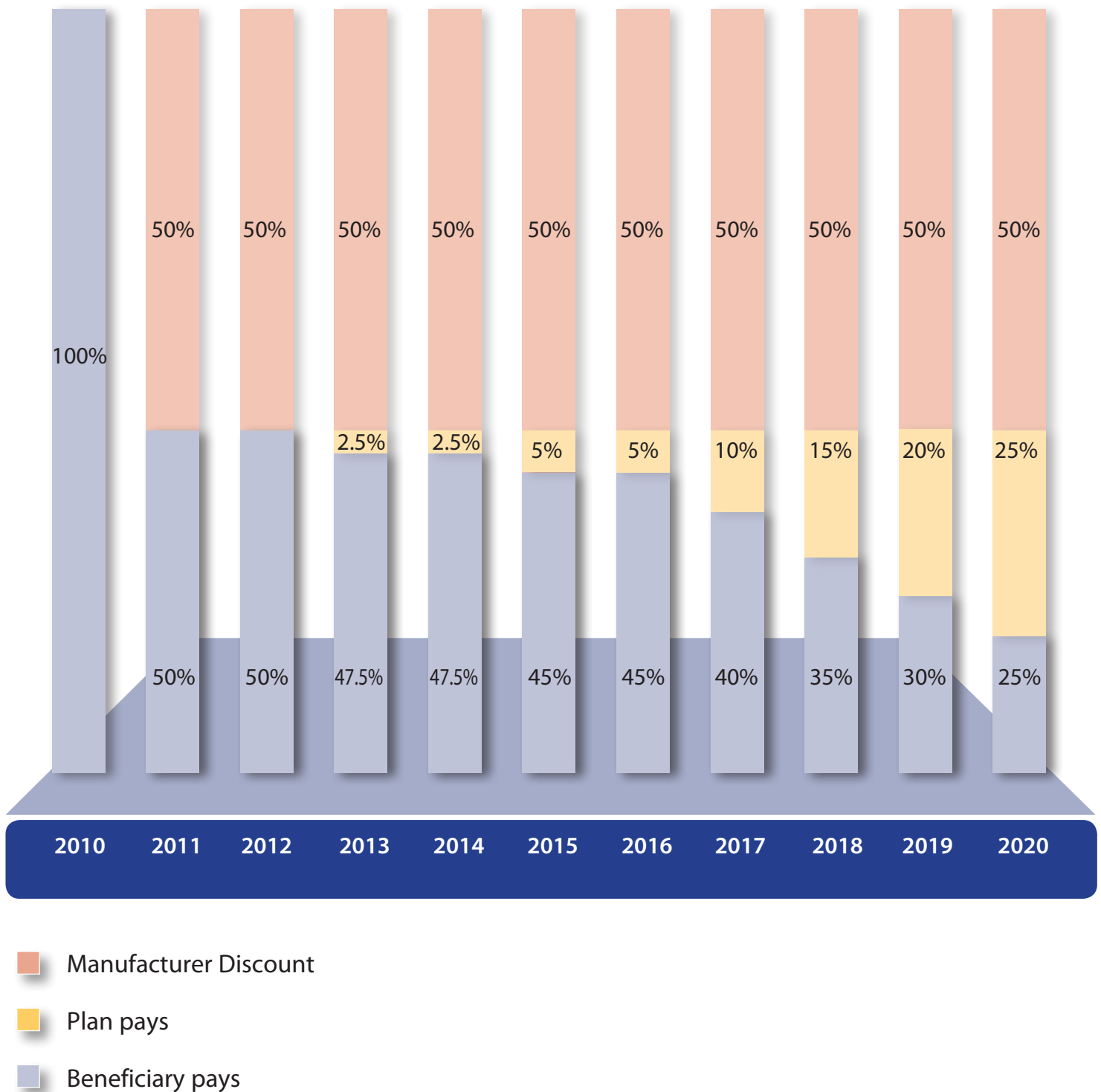
What happens if only a portion of the claim is in the gap?

The 50% discount will only apply to the portion of the claim that's in the coverage gap. For example, if someone fills a \$100 prescription when he or she is \$50 away from reaching the coverage gap, only the \$50 in the coverage gap is subject to the discount.

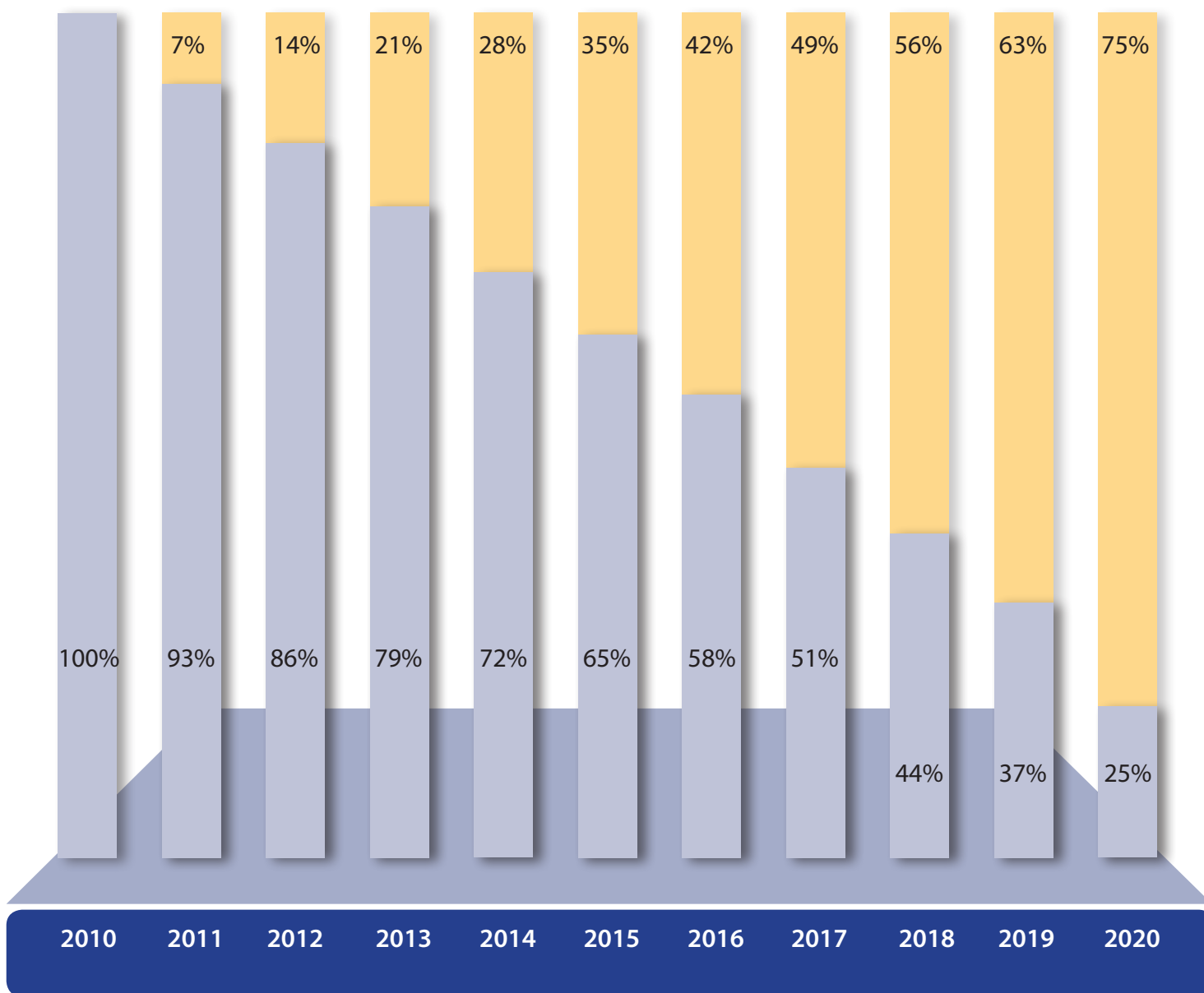
What additional discounts and savings will people with Medicare have over time in the coverage gap?

- In 2011, people with Medicare will pay 50% for applicable drugs, and 93% for all other covered drugs.
- Over the next 10 years, the benefits will increase for all covered drugs so that people with Medicare will pay less in the coverage gap.
- By 2020, the coverage gap will close and people will pay only 25% for covered brand-name and generic drugs from the time they meet the deductible (if applicable) until they reach the out-of-pocket limit.

Brand-Name Prescription Drug Savings in the Coverage Gap



Generic Drug Savings in the Coverage Gap



■ Plan pays
■ Beneficiary pays

